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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/779,599	01/07/97	GOEDDEL	D P089702
EXAMINER			
18N2/0708			
GINGER R DREGER GENENTECH INC 460 POINT SAN BRUNO BOULEVARD SOUTH SAN FRANCISCO CA 94080-4990			
1812			PAPER NUMBER 6

DATE MAILED: 07/08/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on _____
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 31 to 33 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 31 to 33 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

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- 1) Claims 31 to 33 are pending in the instant application.
- 2) The first sentence of the instant specification has been amended to claim benefit of priority under 35 U.S.C. § 120 from one or more previous applications. This amendment attempts to incorporate the content of one or more prior applications into the instant specification by reference. Whereas the claim for priority under 35 U.S.C. § 120 is proper and can be made at any point during the prosecution of a patent application, the incorporation of material by reference constitutes new matter whose entry is prohibited by 35 U.S.C. § 132. New material can only be introduced into an application if that material is contained in an amendment which has been filed concurrently with the application under 37 C.F.R. § 1.53 **and** wherein the amendment is referred to in the oath or declaration **filed therewith**. See M.P.E.P. 608.04(b). Applicant is required to cancel the new matter in the response to this Office action.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 3) Claims 31 to 33 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which is not

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described in the instant specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claim invention or to enable one skilled in the art to make and use the claimed invention. The instant claims are directed to a human protein which associates with the cytoplasmic domain of a tumor necrosis factor (TNF) receptor. The instant specification, however, does not describe even a single protein of human origin which meets the limitations of the instant claims. The instant specification describes the isolation of cDNAs encoding two TNF receptor associated factor (TRAF) proteins of murine origin and the isolation of the proteins encoded thereby. It also contains ample suggestions that homologous human proteins could be isolated by employing those methods that are routine in the art of molecular biology. The instant specification provides no structural or functional information about a human TRAF and no evidence that the murine TRAFs disclosed therein are functionally or structurally predictive of homologous proteins from any other animal. In fact, the abstract of the Lewis et al. publication (P.N.A.S. 88:2830-2834, Apr. 1991), which was cited by Applicant, states that the amino acid sequences of the human and murine homologs of the type 1 TNF receptor are only 64% identical and that the amino acid sequences of the human and murine homologs of the type 2 TNF receptor are

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only 62% identical. Since the TNF receptors are not structurally and functionally conserved between mammalian species an artisan would not reasonably expect the proteins associated therewith to be conserved between mice and humans. Therefore, the description of a cDNA encoding a TRAF protein and the protein encoded thereby from a mouse does not provide a practitioner of the art with sufficient written description to enable them to make and use a human TRAF protein.

4) Claims 31 to 33 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 31 to 33 are vague and indefinite because the instant specification does not identify that material property of combination of properties which is unique to and, therefore, definitive of a TRAF protein. The limitation "obtainable" in claim 31 is a functional limitation whereas claim 31 is drawn to a composition of matter. *In re Hutchison*, 69 USPQ 138 (CCPA 1946) held that functional statements contained therein do not limit article claims. Claim 31, therefore, simply encompasses a human "TRAF" and the instant specification does not provide an unambiguous material definition of this term. Claim 31 is essentially a single means claim since it encompasses any protein of human origin which is capable of interacting with the

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cytoplasmic domain of any protein that can function as a TNF receptor.

Claims 32 and 33 are incorrect because there is no antecedent basis for "the" human homolog. There is no evidence of record that humans only produce one protein which is homologous to either of the two murine TRAF proteins disclosed in the instant specification since there are different allelic forms of many proteins within the population of a given species.

Claim 31 is vague and indefinite because it recites nucleic acid hybridization as a limitation without reciting the conditions under which this property is to be determined. It is incorrect because an oligonucleotide "sequence" is a property of a molecule and not a material entity in and of itself. Therefore, a "sequence" is incapable of hybridizing to anything. It is also vague and indefinite because the meets and bounds of "derived from" can not be determined.

5) Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stephen Walsh, can be reached at (703) 308-2957.

Official papers filed by fax should be directed to (703) 308-4227.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. § 132 or which otherwise require a signature, may be used by Applicant and should be addressed to [stephen.walsh@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees will not engage in Internet

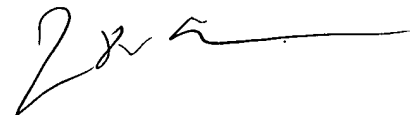
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communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. § 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on 25 February of 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



JOHN ULM
PRIMARY EXAMINER
GROUP 1800